

DEPARTMENT OF HEALTH AND HUMAN SERVICES			
FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Minneapolis District 240 Hennipin Ave. Minneapolis, MN 55401 (612) 787-3904		DATE(S) OF INSPECTION Jan. 5-7, 2000	
		FEI NUMBER 0000112233	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: William S. Gundstrom, Vice President Production			
FIRM NAME Topline Pharmaceuticals, "T.L.P."		STREET ADDRESS 2136 Elbe Place	
CITY, STATE AND ZIP CODE Jackston, MN 55326		TYPE OF ESTABLISHMENT INSPECTED Tablet Repacker	
<p>DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:</p> <p>List your observations in a logical and concise manner.</p> <p>(See IOM 512, 512.1, & 512.2)</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sidney H. Rogers	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Sidney H. Rogers, Investigator	DATE ISSUED 1-07-00

The observations of objectionable conditions and practices listed on the front of this form are reported:

- 1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or**
- 2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.**

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

(Reverse of Form FDA 483)